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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,359	10/20/2003	Natarajan Ranganathan	KBI-0015	4537

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EXAMINER

DAVIS, RUTH A

ART UNIT PAPER NUMBER

1651

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/689,359

Applicant(s)

RANGANATHAN, NATARAJAN

Examiner

Ruth A. Davis

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2/04/1/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Priority***

1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence(s) of the specification or in an application data sheet by identifying the prior application by application number (37 CFR 1.78(a)(2) and (a)(5)). If the prior application is a non-provisional application, the specific reference must also include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

The instant specification fails to identify the current status of the parent cases.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2, 3 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In claim 2, the term “S. thermophilus” should first be spelled out, then followed by the abbreviation. It is unclear to what genus the claim refers.

Claim 3 is rendered vague and indefinite for reciting “such as” in line 4, because it is unclear if the limitations following the phrase is intended to be a limitation or not. Moreover, it is unclear if applicant intends the claim to include sorbitol, mannitol, and xylitol as an option for the carbohydrate. It is further noted that the claim repeats the phrase “brown sugar” in lines 5 and 6.

In claim 7, the term “at least one prebiotic ingredient” lacks sufficient antecedent basis.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 – 3 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Halpin-Dohnalek et al. (US 5902578 A).

Applicant claims a nutritional food or product comprising at least one probiotic bacteria, carbohydrate, fat and protein ingredient. The probiotic bacteria is selected from Lactobacillus acidophilus, L. bulgaricus, L. casei, L. rhamnosus, L. fermentum, L. salivaroos, L. brevis, L. plantarum, L. ruteri, S. thermophilus, Bacillus sporogenes, Bifidobacterium adolescentis, B.

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infantis, *B. longum*, *B. thermophilus* or *B. bifidum*; and wherein the product provides 5 – 20 billion CFUs; the carbohydrate is selected from dextrose, sucrose, fructose, lactose, maltose, galactose, sugar alcohols, invert sugars, sugar syrups, brown sugar, corn syrup, corn syrup, corn syrup solids, honey, molasses, maple syrup, fruit juices, stevia and artificial sweeteners; and the composition further comprises at least one vitamin and mineral

Halpin-Dohnalek teaches a nutritional composition comprising protein, fat, carbohydrates and the probiotic *Lactobacillus reuteri*, *L. acidophilus* and *Bifidobacterium infantis* (abstract). The reference teaches that the composition is useful for maintaining GI health, and teaches a method for restoring GI health by administering the composition (abstract). Halpin-Dohnalek additionally teaches the compositions further comprising minerals and vitamins (col.3 line 30-50) as well as sucrose (claims). Halpin-Dohnalek provides examples of the composition wherein the compositions provide  $10 \times 10^9$  –  $5 \times 10^9$  (or 5 – 10 billion) CFUs of bacteria of *L. reuteri* (example 1).

The reference anticipates the claimed subject matter.

6. Claims 1, 3 – 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Jungvid (US 5085874 A).

Applicant claims a nutritional food or product comprising at least one probiotic bacteria, carbohydrate, fat and protein ingredient. The carbohydrate is selected from dextrose, sucrose, fructose, lactose, maltose, galactose, sugar alcohols, invert sugars, sugar syrups, brown sugar, corn syrup, corn syrup, corn syrup solids, honey, molasses, maple syrup, fruit juices, stevia and artificial sweeteners; the fat is selected from olive, canola, palm, coconut, sunflower, peanut,

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vegetable, fish, cotton seed, or soybean oils; lecithin, lard, monoglycerides, diglycerides, butter, margarin, and other animal, vegetable, marine or milk fats; the protein is selected from cereal, milk, egg, animal, vegetable, whey, bean, or soy proteins, lactalbumin-casein co-precipitate, calcium caseinate, sodium caseinate, or peanuts. The composition further comprises at least one vitamin and mineral. Applicant additionally claims a nutritional food or product for maintaining or enhancing GI health, comprising at least one carbohydrate, fat, protein, vitamin, mineral, prebiotic and probiotic, wherein the probiotic has a propensity to hydrolyze nitrogenous waste products

Jungvid teaches nutritional compositions comprising vegetable proteins, whey, vitamins, sodium caseinate, fat (lard, soy oil), animal proteins, starch (a prebiotic), dextrose (carbohydrate), minerals, probiotics (*Lactobacillus bulgaricus*, which hydrolyzes nitrogenous waste products) and lactulose (example 1).

The reference anticipates the claimed subject matter.

7. Claims 1, 3 – 5, 7 and 9 – 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Paul (US 5744134 A).

Applicant claims a nutritional food or product comprising at least one probiotic bacteria, carbohydrate, fat and protein ingredient. The carbohydrate is selected from dextrose, sucrose, fructose, lactose, maltose, galactose, sugar alcohols, invert sugars, sugar syrups, brown sugar, corn syrup, corn syrup, corn syrup solids, honey, molasses, maple syrup, fruit juices, stevia and artificial sweeteners; the fat is selected from olive, canola, palm, coconut, sunflower, peanut, vegetable, fish, cotton seed, or soybean oils; lecithin, lard, monoglycerides, diglycerides, butter,

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margarin, and other animal, vegetable, marine or milk fats; the protein is selected from cereal, milk, egg, animal, vegetable, whey, bean, or soy proteins, lactalbumin-casein co-precipitate, calcium caseinate, sodium caseinate, or peanuts. The composition further comprises at least one prebiotic selected from FOS, galacto-oligosaccharide, isomalto-oligosaccharide, a xylo-oligosaccharide, isomalto-oligosaccharide, Jerusalem artichoke flour, rolled oats, banana fiber, a pectin, pectin oligosaccharides, mannan, pentosan, beta-glucan, rabin or galactan. Applicant finally claims a method for restoring and maintaining GI health, comprising administering to a subject at least one food or nutritional product comprising an effective amount of probiotic bacteria and an effective amount of a prebiotic; and a nutraceutical composition to alleviate symptoms of uremia, comprising a probiotic, prebiotic, and an ammoniaphilic urea degrading microorganism with pH stability and urea degrading activity.

Paul teaches compositions for restoring and maintaining GI health, comprising immunoglobulins (protein), FOS (prebiotic), pectin (prebiotic), Lactobacillus and Bifidobacteria (abstract). The immunoglobulin, or protein, is derived from milk or whey (abstract); and the Lactobacillus may be *L. acidophilus*, *bulgaricus*, *casei*, *fermentum*, *salivarius*, *brevis*, *plantarum*, *Bifidobacterium adolescentis*, *infantis*, *longum*, *thermophilus*, or *bifidum* (col.4 line 20-29). The composition further comprises carbohydrates such as maltodextrin and lactose, and lipids such as lecithin (col.5 line 40-45). Paul additionally teaches methods for restoring and maintaining GI health, comprising administering the composition (col.4 line 40-45).

Although Paul does not specifically teach that the bacteria are ammoniaphilic urea degrading microorganisms with pH stability and urea degrading activity, the disclosed bacteria

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are the same as those claimed. Thus the bacteria of the cited reference must also, intrinsically, have the same characteristics.

Therefore the reference anticipates the claimed subject matter.

8. Claims 1, 3 – 5, 7 and 10 – 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Costanzo et al. (US 5518740).

Applicant claims a nutritional food or product comprising at least one probiotic bacteria, carbohydrate, fat and protein ingredient. The carbohydrate is selected from dextrose, sucrose, fructose, lactose, maltose, galactose, sugar alcohols, invert sugars, sugar syrups, brown sugar, corn syrup, corn syrup solids, honey, molasses, maple syrup, fruit juices, stevia and artificial sweeteners; the fat is selected from olive, canola, palm, coconut, sunflower, peanut, vegetable, fish, cotton seed, or soybean oils; lecithin, lard, monoglycerides, diglycerides, butter, margarin, and other animal, vegetable, marine or milk fats; the protein is selected from cereal, milk, egg, animal, vegetable, whey, bean, or soy proteins, lactalbumin-casein co-precipitate, calcium caseinate, sodium caseinate, or peanuts. The composition further comprises a prebiotic selected from FOS, galacto-oligosaccharide, isomalto-oligosaccharide, a xylo-oligosaccharide, isomalto-oligosaccharide, Jerusalem artichoke flour, rolled oats, banana fiber, a pectin, pectin oligosaccharides, mannan, pentosan, beta-glucan, rhaman or galactan. Applicant claims a nutraceutical composition to alleviate symptoms of uremia, comprising a probiotic, prebiotic, and an amoniaphilic urea degrading microorganism with pH stability and urea degrading activity; and a yogurt or yogurt based product comprising at least one probiotic, carbohydrate and protein.



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Costanzo teaches a yogurt composition (abstract) comprising *Lactobacillus bulgaricus* (probiotic), whole milk (milk proteins), dextrose (carbohydrate) and inulin (a prebiotic) (example 1). Costanzo additionally teaches the yogurts comprising *Lactobacillus bulgaricus*, whole milk (milk proteins), dextrose (carbohydrate), banana smash (prebiotic, or banana fiber), and soy lecithin (fat) (example 2). The compositions may alternatively comprise pectin (prebiotic) (example 3).

Although Costanzo does not specifically teach that the bacteria are ammoniaphilic urea degrading microorganisms with pH stability and urea degrading activity, the disclosed bacteria are the same as those claimed. Thus the bacteria of the cited reference must also, intrinsically, have the same characteristics.

Therefore the reference anticipates the claimed subject matter.

### ***Double Patenting***

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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10. Claim 10 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. Patent No. 6706287. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claim is to a a nutraceutical composition to alleviate symptoms of uremia, comprising a probiotic, prebiotic, and an amoniaphilic urea degrading microorganism with pH stability and urea degrading activity. The claim of the patent contains the above components with more additives. Therefore the instant composition encompasses the composition of the cited patent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Ruth A. Davis

March 4, 2005

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LEON B. LANKFORD, JR.  
PRIMARY EXAMINER